

Claims

We claim:

- 5 1. A method for diagnosis of a condition, disease, or disorder, comprising:
 - (a) administering to a patient a composition comprising at least one nanoparticle-based assembly, wherein the nanoparticle-based assembly comprises a nanoparticle; a surrogate marker, and a means for detecting a specific chemical entity (SCE);
 - 10 (b) obtaining a sample of bodily fluid from the patient;
 - (c) applying sensor technology to the sample of bodily fluid to detect the presence of the surrogate marker.
- 15 2. The method according to claim 1, wherein the nanoparticle is a nanotube.
3. The method according to claim 1, wherein SCE-detecting means is selected from the group consisting of an antibody, a protein, and an aptamer.
- 20 4. The method according to claim 1, wherein the surrogate marker is selected from the group consisting of DMSO, benzodiazepine, a benzodiazepine metabolite, acetaldehyde, acetophenone, anise, benzaldehyde, benzyl alcohol, benzyl cinnamate, cadinene, camphene, camphor, cinnamon, citronellal, cresol, cyclohexane, eucalyptol, and eugenol, eugenyl methyl ether.
- 25 5. The method according to claim 1, wherein the surrogate marker is selected from the group consisting of sodium bisulfate, dioctyl sodium sulfosuccinate, polyglycerol polyricinoleic acid, calcium casein peptone-calcium phosphate, botanicals (*i.e.*, chrysanthemum; licorice; jellywort, honeysuckle; lophatherum, mulberry leaf; frangipani; selfheal; sophora flower bud), ferrous bisglycinate chelate, seaweed-derived calcium, DHASCO (docosahexaenoic acid-rich single-cell oil) and ARASCO (arachidonic acid-rich single-cell oil), fructooligosaccharide, trehalose, gamma cyclodextrin, phytosterol esters, gum arabic, potassium bisulfate, stearyl alcohol, erythritol, D-tagatose, and mycoprotein.

6. The method according to claim 1, wherein the bodily fluid sample is selected from the group consisting of exhaled breath, whole blood, blood plasma, urine, semen, saliva, lymph fluid, meningeal fluid, amniotic fluid, glandular fluid, 5 sputum, feces, sweat, mucous, and cerebrospinal fluid.

7. The method according to claim 1, wherein the bodily fluid sample is a separated fraction of a solution or mixture containing homogenized solid materials selected from the group consisting of feces, tissues, and biopsy samples.

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8. The method according to claim 1, wherein the SCE-detecting means has a specific action on compounds selected from the group consisting of acetaldehyde, acetone, ammonia, carbon monoxide, chloroform, diethylamine, hydrogen, isoprene, methanethiol, methylethylketone, O-toluidine, pentane sulfides and sulfides, H₂S, 15 MeS, Me₂S, α II-spectrin breakdown products and/or isoprostanes, prostate specific antigen, and GLXA.

20 9. The method according to claim 1, wherein the SCE-detecting means has a specific action on compounds selected from the group consisting of illicit, illegal, or controlled substances; allergens; toxins; carcinogens; infectious agents; and cell markers for diseases.

25 10. The method according to claim 1, wherein the SCE-detecting means has a specific action on compounds selected from the group consisting of amphetamines, analgesics, barbiturates, club drugs, cocaine, crack cocaine, depressants, designer drugs, ecstasy, Gamma Hydroxy Butyrate, hallucinogens, heroin, morphine, inhalants, ketamine, lysergic acid diethylamide, marijuana, methamphetamines, opiates, narcotics, phencyclidine, prescription drugs, psychedelics, Rohypnol, steroids, stimulants, pollen, spores, dander, peanuts, eggs, shellfish, mercury, lead, other heavy 30 metals, *Clostridium Difficile* toxin, acetaldehyde, beryllium compounds, chromium, dichlorodiphenyltrichloroethane (DDT), estrogens, N-methyl-N'-nitro-N-nitrosoguanidine (MNNG), radon, *Bordetella bronchiseptica*, *citrobacter*, *Escherichia coli*, hepatitis viruses, herpes, immunodeficiency viruses, influenza virus,

Listeria, *micrococcus*, *mycobacterium*, *rabies virus*, *rhinovirus*, *rubella virus*, *Salmonella*, *yellow fever virus*, *T cell markers*, *B cell markers*, *myeloid/monocytic markers*, *maturity status markers*, α -*Fetoprotein*, $\beta 2$ -*Microglobulin*, and *Beta Human Chorionic Gonadotropin (b HCG)*.

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11. The method according to claim 1, wherein the nanoparticle is formed with an interior void that contains the surrogate marker, wherein the nanoparticle has at least one open end to provide access to the interior void.

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12. The method according to claim 11, wherein the interior void also contains a payload.

13. The method according to claim 11, wherein the nanoparticles further includes an end-cap to block the open end.

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14. The method according to claim 13, wherein the end-cap is a particle that has a maximum dimension of less than 100 μm .

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15. The method according to claim 13, wherein the end-cap is attached to the nanoparticle by covalent bonds.

16. The method according to claim 13, wherein the nanoparticle is in the form of a tubular body; and wherein the SCE-detecting means is attached to the end-cap.

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17. The method according to claim 1, wherein the nanoparticle is composed of silica.

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18. The method according to claim 1, wherein the nanoparticle is composed of a polymer.

19. The method according to claim 18, wherein the SCE-detecting means is attached to a surface of the nanoparticle using copolymerization.

20. The method according to claim 18, wherein the polymer nanoparticle is composed of polymers selected from the group consisting of polystyrene, polyorganosiloxane, poly(methyl methacrylate), polystyrene, polylactic acids, and other biodegradable polymers, acrylic latexes, polyorganosiloxane, cellulose, 5 polyethylene, poly(vinyl chloride), poly(ethyl methacrylate), poly(tetrafluoroethylene), poly(4-iodostyrene/divinylbenzene), poly(4-vinylpyridine/divinylbenzene), poly(styrene/divinyl benzene), crosslinked melamine particles, phenolic polymer colloids, polyamide 6/6, natural rubber, and naturally occurring biopolymers.

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21. The method according to claim 18, wherein the polymer nanoparticle is composed of biodegradable polymers selected from the group consisting of poly(caprolactone), poly(glycolic acid), poly(lactic acid), poly(hydroxybutyrate), poly(adipic anhydride), poly(maleic anhydride), polydioxanone, polyamines, 15 polyamides, polyurethanes, polyesteramides, polyorthoesters, polyacetals, polyketals, polycarbonates, polyorthocarbonates, polyphosphazenes, poly(malic acid), poly(amino acids), polyvinylpyrrolidone, poly(methyl vinyl ether), poly(alkylene oxalate), poly(alkylene succinate), polyhydroxycellulose, chitin, chitosan, and copolymers.

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22. The method according to claim 18, wherein the polymer nanoparticle is composed of biocompatible polymers selected from the group consisting of poly(lactide-co-glycolide), poly(ethylene glycol), and copolymers of poly(ethylene oxide) with poly(L-Lactic acid) or with poly(β -benzyl-L-aspartate).

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23. The method according to claim 1, wherein the SCE-detecting means is incorporated into the nanoparticle.

30 24. The method according to claim 1, wherein the nanoparticle is produced in a shape selected from a group consisting of spherical; elliptical; cubic; cylindrical; tetrahedron; polyhedral; irregular-prismatic; icosahedral; and cubo-octahedral.

25. The method according to claim 1, wherein the nanoparticle has a dimension less than 500 nm.

26. The method according to claim 1, wherein the surface of the nanoparticle is stealthy.

27. A method for diagnosis and treatment of a condition, disease, or disorder, comprising:

10 (a) administering to a patient a composition comprising at least one nanoparticle-based assembly, wherein the nanoparticle-based assembly comprises a nanoparticle; a surrogate marker, a means for detecting a specific chemical entity (SCE), and a payload;

15 (b) obtaining a sample of bodily fluid from the patient;

(c) applying sensor technology to the sample of bodily fluid to detect the presence of the surrogate marker.

28. The method according to claim 27, wherein the nanoparticle is a nanotube.

20 29. The method according to claim 27, wherein SCE-detecting means is selected from the group consisting of an antibody, a protein, and an aptamer.

25 30. The method according to claim 27, wherein the surrogate marker is selected from the group consisting of benzodiazepine, a benzodiazepine metabolite, acetaldehyde, DMSO, acetophenone, anise, benzaldehyde, benzyl alcohol, benzyl cinnamate, cadinene, camphene, camphor, cinnamon, citronellal, cresol, cyclohexane, eucalyptol, and eugenol, eugenyl methyl ether.

30 31. The method according to claim 27, wherein the surrogate marker is selected from the group consisting of sodium bisulfate, dioctyl sodium sulfosuccinate, polyglycerol polyricinoleic acid, calcium casein peptone-calcium phosphate, botanicals (*i.e.*, chrysanthemum; licorice; jellywort, honeysuckle; lophatherum, mulberry leaf; frangipani; selfheal; sophora flower bud), ferrous bisglycinate chelate,

seaweed-derived calcium, DHASCO (docosahexaenoic acid-rich single-cell oil) and ARASCO (arachidonic acid-rich single-cell oil), fructooligosaccharide, trehalose, gamma cyclodextrin, phytosterol esters, gum arabic, potassium bisulfate, stearyl alcohol, erythritol, D-tagatose, and mycoprotein.

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32. The method according to claim 27, wherein the bodily fluid sample is selected from the group consisting of exhaled breath, whole blood, blood plasma, urine, semen, saliva, lymph fluid, meningeal fluid, amniotic fluid, glandular fluid, sputum, feces, sweat, mucous, and cerebrospinal fluid.

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33. The method according to claim 27, wherein the bodily fluid sample is a separated fraction of a solution or mixture containing homogenized solid materials selected from the group consisting of feces, tissues, and biopsy samples.

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34. The method according to claim 27, wherein the SCE-detecting means has a specific action on compounds selected from the group consisting of acetaldehyde, acetone, ammonia, carbon monoxide, chloroform, diethylamine, hydrogen, isoprene, methanethiol, methylethylketone, O-toluidine, pentane sulfides and sulfides, H₂S, MeS, Me₂S, α II-spectrin breakdown products and/or isoprostanes, prostate specific antigen, and GLXA.

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35. The method according to claim 27, wherein the SCE-detecting means has a specific action on compounds selected from the group consisting of illicit, illegal, or controlled substances; allergens; toxins; carcinogens; infectious agents; and cell markers for diseases.

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36. The method according to claim 27, wherein the SCE-detecting means has a specific action on compounds selected from the group consisting of amphetamines, analgesics, barbiturates, club drugs, cocaine, crack cocaine, depressants, designer drugs, ecstasy, Gamma Hydroxy Butyrate, hallucinogens, heroin, morphine, inhalants, ketamine, lysergic acid diethylamide, marijuana, methamphetamines, opiates, narcotics, phencyclidine, prescription drugs, psychedelics, Rohypnol, steroids, stimulants, pollen, spores, dander, peanuts, eggs, shellfish, mercury, lead, other heavy

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metals, *Clostridium Difficile* toxin, acetaldehyde, beryllium compounds, chromium, dichlorodiphenyltrichloroethane (DDT), estrogens, N-methyl-N'-nitro-N-nitrosoguanidine (MNNG), radon, *Bordetella bronchiseptica*, citrobacter, *Escherichia coli*, hepatitis viruses, herpes, immunodeficiency viruses, influenza virus, *Listeria*, micrococcus, mycobacterium, rabies virus, rhinovirus, rubella virus, *Salmonella*, yellow fever virus, T cell markers, B cell markers, myeloid/monocytic markers, maturity status markers, α -Fetoprotein, β 2-Microglobulin, and Beta Human Chorionic Gonadotropin (b HCG).

10 37. The method according to claim 27, wherein the nanoparticle is formed with an interior void that contains the surrogate marker, wherein the nanoparticle has at least one open end to provide access to the interior void.

15 38. The method according to claim 37, wherein the interior void also contains a payload.

39. The method according to claim 37, wherein the nanoparticles further includes an end-cap to block the open end.

20 40. The method according to claim 39, wherein the end-cap is a particle that has a maximum dimension of less than 100 μm .

41. The method according to claim 39, wherein the end-cap is attached to the nanoparticle by covalent bonds.

25 42. The method according to claim 39, wherein the nanoparticle is in the form of a tubular body; and wherein the SCE-detecting means is attached to the end-cap.

30 43. The method according to claim 27, wherein the nanoparticle is composed of silica.

44. The method according to claim 27, wherein the nanoparticle is composed of a polymer.

5 45. The method according to claim 44, wherein the SCE-detecting means is attached to a surface of the nanoparticle using copolymerization.

10 46. The method according to claim 44, wherein the polymer nanoparticle is composed of polymers selected from the group consisting of polystyrene, polyorganosiloxane, poly(methyl methacrylate), polystyrene, polylactic acids, and other biodegradable polymers, acrylic latexes, polyorganosiloxane, cellulose, polyethylene, poly(vinyl chloride), poly(ethyl methacrylate), poly(tetrafluoroethylene), poly(4-iodostyrene/divinylbenzene), poly(4-vinylpyridine/divinylbenzene), poly(styrene/divinyl benzene), crosslinked melamine particles, phenolic polymer colloids, polyamide 6/6, natural rubber, and naturally occurring biopolymers.

15 47. The method according to claim 44, wherein the polymer nanoparticle is composed of biodegradable polymers selected from the group consisting of poly(caprolactone), poly(glycolic acid), poly(lactic acid), poly(hydroxybutyrate), poly(adipic anhydride), poly(maleic anhydride), polydioxanone, polyamines, polyamides, polyurethanes, polyesteramides, polyorthoesters, polyacetals, polyketals, polycarbonates, polyorthocarbonates, polyphosphazenes, poly(malic acid), poly(amino acids), polyvinylpyrrolidone, poly(methyl vinyl ether), poly(alkylene oxalate), poly(alkylene succinate), polyhydroxycellulose, chitin, chitosan, and copolymers.

20 48. The method according to claim 44, wherein the polymer nanoparticle is composed of biocompatible polymers selected from the group consisting of poly(lactide-co-glycolide), poly(ethylene glycol), and copolymers of poly(ethylene oxide) with poly(L-Lactic acid) or with poly(β -benzyl-L-aspartate).

25 49. The method according to claim 27, wherein the SCE-detecting means is incorporated into the nanoparticle.

50. The method according to claim 27, wherein the nanoparticle is produced in a shape selected from a group consisting of spherical; elliptical; cubic; cylindrical; tetrahedron; polyhedral; irregular-prismatic; icosahedral; and cubo-octahedral.

5 51. The method according to claim 27, wherein the nanoparticle has a dimension less than 500 nm.

10 52. The method according to claim 27, wherein the surface of the nanoparticle is stealthy.

15 53. The method according to claim 27, wherein the payload is selected from the group consisting of genetic materials; RNA; oligonucleotides; polynucleotides; peptides; proteins; enzymes; hormones; steroids; chemotherapeutics; antibiotics; antifungal agents; anesthetics; immunomodulators; anti-inflammatory agents; pain relieving agents; autonomic drugs; cardiovascular-renal drugs; endocrine drugs; hematopoietic growth factors; blood lipid lowering drugs; AIDS drugs; modulators of smooth muscle function; antileptics; psychoactive drugs; and drugs that act on the peripheral nerves, adrenergic receptors, cholinergic receptors, the skeletal muscles, the cardiovascular system, smooth muscles, the blood circulatory system, synoptic sites, neuroeffector junctional sites, endocrine and hormone systems, metabolic systems, the immunological system, the reproductive system, the skeletal system, autacoid systems, the alimentary and excretory systems, the histamine system, and the central nervous system.

20 25 54. The method according to claim 53, wherein the payload is selected from the group consisting of prochlorperazine edisylate, ferrous sulfate, aminocaproic acid, mecamylamine hydrochloride, procainamide hydrochloride, amphetamine sulfate, methamphetamine hydrochloride, benzamphetamine hydrochloride, isoproterenol sulfate, phenmetrazine hydrochloride, bethanechol chloride, methacholine chloride, pilocarpine hydrochloride, atropine sulfate, scopolamine bromide, isopropamide iodide, tridihexethyl chloride, phenformin hydrochloride, methylphenidate hydrochloride, theophylline cholate, cephalexin hydrochloride, diphenidol, meclizine hydrochloride, prochlorperazine maleate, phenoxybenzamine,

thiethylperzine maleate, anisindone, diphenadione erythryl tetranitrate, digoxin, Intal (disodium cromoglycate), codeine, morphine, sodium salicylate, salicylic acid, meperidine hydrochloride (DEMEROL), chlophedianol hydrochloride, epinephrine, isoproterenol, salbutamol, terbutaline, ephedrine, aminophylline, acetylcysteine, sulfanilamide, sulfadiazine, tetracycline, rifampin (rifamycin), dihydrostreptomycin, p-aminosalicylic acid, hypoglycemics tolbutamide (ORINASE), prednisone, prednisolone, prednisolone metasulfobenzoate, chlorambucil, busulfan, alkaloids, antimetabolites, 6-mercaptopurine, thioguanine, 5-fluorouracil, hydroxyurea, isofluorophate, acetazolamide, methazolamide, bendroflumethiazide, chloropromazine, tolazamide, chlormadinone acetate, phenaglycodol, allopurinol, aluminum aspirin, methotrexate, acetyl sulfisoxazole, erythromycin, hydrocortisone, hydrocorticosterone acetate, cortisone acetate, dexamethasone and its derivatives such as betamethasone, triamcinolone, methyltestosterone, 17-S-estradiol, ethinyl estradiol, ethinyl estradiol 3-methyl ether, 17- α -hydroxyprogesterone acetate, 19-norprogesterone, norgestrel, norethindrone, norethisterone, norethiederone, progesterone, norgesterone, norethynodrel, aspirin, indomethacin, naproxen, fenoprofen, sulindac, indoprofen, nitroglycerin, isosorbide dinitrate, propranolol, timolol, atenolol, alprenolol, crimetine, clonidine, imipramine, levodopa, chlorpromazine, methyldopa, dihydroxyphenylanine, theophylline, calcium gluconate, ketoprofen, ibuprofen, cephalexin, erythromycin, haloperidol, zomepirac, ferrous lactate, vincamine, phenoxybenzamine, diltiazem, milrinone, mandol, quanbenz, hydrochlorothiazide, ranitidine, flurbiprofen, fenufen, fluprofen, tolmetin, alclofenac, mefenamic, flufenamic, difenac, nimodipine, nitrendipine, nisoldipine, nicardipine, felodipine, lidoflazine, tiapamil, gallopamil, amlodipine, mioflazine, lisinopril, enalapril, enalaprilat, captopril, ramipril, famotidine, nizatidine, sucralfate, etintidine, tetratolol, minoxidil, chlordiazepoxide, diazepam, amitriptyline, and imipramine.

55. The method according to claim 53, wherein the payload is selected from the group consisting of bone morphogenic proteins, insulin, colchicines, glucagons, 30 thyroid stimulating hormone, parathyroid hormones, pituitary hormones, calcitonin, rennin, prolactin, corticotrophin, thyrotropic hormone, follicle stimulating hormone, chorionic gonadotropin, gonadotropin releasing hormone, bovine somatotropin, porcine somatotropin, oxytocin, vasopressin, GRF, somatostatin, lypressin,

pancreozymin, luteinizing hormone, LHRH, LHRH agonists and antagonists, leuprolide, interferons, consensus interferon, interleukins, growth hormones, bovine growth hormone, porcine growth hormone, fertility inhibitors, fertility promoters, growth factors, coagulation factors, and human pancreas hormone releasing factor.

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56. The method according to claim 53, wherein the payload is a chemotherapeutic selected from the group consisting of carboplatin, cisplatin, paclitaxel, BCNU, vincristine, camptothecin, etoposide, cytokines, ribozymes, interferons, oligonucleotides, and oligonucleotides that inhibit translation or transcription of tumor genes.

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57. A method of monitoring a patient during administration of at least one therapeutic drug, said method comprising:

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administering to the patient at least one therapeutic drug;
exposing at least one sensor to expired gases from the patient;
detecting one or more target markers from the therapeutic drug with said sensor.

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58. The method of claim 57 wherein said target marker is the therapeutic drug.

59. The method of claim 57 wherein said target marker is a metabolite of the therapeutic drug indicative of the therapeutic drug.

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60. The method of claim 57 wherein said target marker is selected from a group consisting of dimethyl sulfoxide (DMSO), acetaldehyde, acetophenone, trans-Anethole (1-methoxy-4-propenyl benzene) (anise), benzaldehyde (benzoic aldehyde), benzyl alcohol, benzyl cinnamate, cadinene, camphene, camphor, cinnamaldehyde (3-phenylpropenal), garlic, citronellal, cresol, cyclohexane, eucalyptol, and eugenol, eugenyl methyl ether; butyl isobutyrate (n-butyl 2, methyl propanoate) (pineapple); citral (2-trans-3,7-dimethyl-2,6-heptadiene-1-al); menthol (1-methyl-4-isopropylcyclohexane-3-ol); and α -Pinene (2,6,6-trimethylbicyclo-(3,1,1)-2-heptene).

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61. The method of claim 57 wherein at least one therapeutic drug is administered to the patient orally.

5 62. The method of claim 57 wherein at least one therapeutic drug is delivered intravenously.

63. The method of claim 57 wherein the detecting step comprises detecting both presence and concentration of the target marker to determine at least one therapeutic drug concentration in blood.

10 64. The method of claim 63 further comprising assigning a numerical value to the concentration as analyzed upon reaching a level of therapeutic effect of said therapeutic drug in said patient and, thereafter, assigning higher or lower values to the concentration based on its relative changes.

15 65. The method of claim 64, further comprising monitoring the concentration by monitoring changes in said value and adjusting administration of the therapeutic drug to maintain a desired therapeutic effect.

20 66. The method of claim 63 further comprising determining an appropriate dosage of at least one therapeutic drug based on the concentration of at least one target marker detected in said expired gases.

25 67. The method of claim 57 wherein the steps are repeated periodically to monitor pharmacodynamics and pharmacokinetics of at least one therapeutic drug over time.

68. The method of claim 57 wherein at least one therapeutic drug is for depression.

30 69. The method of claim 57 wherein at least one therapeutic drug is for analgesia.

70. The method of claim 57 wherein at least one therapeutic drug is selected for the treatment of a condition selected from group consisting of rheumatoid arthritis, systemic lupus erythematosus, angina, coronary artery disease, peripheral vascular disease, ulcerative colitis, Crohn's disease, organ rejection, epilepsy, anxiety, 5 degenerative arthritis, vasculitis, and inflammation.

71. The method of claim 57 wherein the detecting is continuous.

72. The method of claim 57 wherein the detecting is periodic.

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73. The method of claim 57 wherein at least one therapeutic drug is selected from the group consisting of: α -Hydroxy-Alprazolam; Acecainide (NAPA); Acetaminophen (Tylenol); Acetylmorphine; Acetylsalicylic Acid (as Salicylates); α -hydroxy-alprazolam; Alprazolam (Xanax); Amantadine (Symmetrel); Ambien (Zolpidem); Amikacin (Amikin); Amiodarone (Cordarone); Amitriptyline (Elavil) & 15 Nortriptyline; Amobarbital (Amytal); Anafranil (Clomipramine) & Desmethylclomipramine; Ativan (Lorazepam); Aventyl (Nortriptyline); Benadryl (Dephenhydramine); Benzodiazepines; Benzoylecgonine; Benztropine (Cogentin); Bupivacaine (Marcaine); Bupropion (Wellbutrin) and Hydroxybupropion; 20 Butabarbital (Butisol); Butalbital (Fiorinal) Carbamazepine (Tegretol); Cardizem (Diltiazem); Carisoprodol (Soma) & Meprobamate; and Celexa (Citalopram & Desmethylcitalopram).

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74. The method of claim 57 wherein at least one therapeutic drug is selected 25 from the group consisting of: Celontin (Methsuximide) (as desmethylmethsuximide); Centrax (Prazepam) (as Desmethyldiazepam); Chloramphenicol (Chloromycetin); Chlordiazepoxide; Chlorpromazine (Thorazine); Chlorpropamide (Diabinese); Clonazepam (Klonopin); Clorazepate (Tranxene); Clozapine; Cocaethylene; Codeine; Cogentin (Benztropine); Compazine (Prochlorperazine); Cordarone (Amiodarone); 30 Coumadin (Warfarin); Cyclobenzaprine (Flexeril); Cyclosporine (Sandimmune); Cylert (Pemoline); Dalmane (Flurazepam) & Desalkylflurazepam; Darvocet; Darvon (Propoxyphene) & Norpropoxyphene; Demerol (Meperidine) & Normeperidine; Depakene (Valproic Acid); Depakote (Divalproex) (Measured as Valproic Acid);

Desipramine (Norpramin); Desmethyl diazepam; Desyrel (Trazodone); Diazepam & Desmethyl diazepam; Diazepam (Valium) Desmethyl diazepam; Dieldrin; Digoxin (Lanoxin); Dilantin (Phenytoin); Disopyramide (Norpace); Dolophine (Methadone); Doriden (Glutethimide); Doxepin (Sinequan) and Desmethyl doxepin; Effexor (Venlafaxine); Ephedrine; Equanil (Meprobamate) Ethanol; Ethosuximide (Zarontin); Ethotoin (Peganone); Felbamate (Felbatol); Fentanyl (Innovar); Fioricet; Fipronil; Flunitrazepam (Rohypnol); Fluoxetine (Prozac) & Norfluoxetine; Fluphenazine (Prolixin); Fluvoxamine (Luvox); Gabapentin (Neurontin); Gamma-Hydroxybutyric Acid (GHB); Garamycin (Gentamicin); Gentamicin (Garamycin); Halazepam (Paxipam); Halcion (Triazolam); Haldol (Haloperidol); Hydrocodone (Hycodan); Hydroxyzine (Vistaril); Ibuprofen (Advil, Motrin, Nuprin, Rufen); Imipramine (Tofranil) and Desipramine; Inderal (Propranolol); Keppra (Levetiracetam); Ketamine; Lamotrigine (Lamictal); Lanoxin (Digoxin); Lidocaine (Xylocaine); Lindane (Gamma-BHC); Lithium; Lopressor (Metoprolol); Lorazepam (Ativan); and Ludiomil.

75. The method of claim 57 wherein at least one therapeutic drug is selected from the group consisting of: Maprotiline; Mebaral (Mephobarbital) & Phenobarbital; Mellaril (Thioridazine) & Mesoridazine; Mephenytoin (Mesantoin); Meprobamate (Miltown, Equanil); Mesantoin (Mephenytoin); Mesoridazine (Serentil); Methadone; Methotrexate (Mexate); Methylsuximide (Celontin) (as desmethylsuximide); Mexiletine (Mexitil); Midazolam (Versed); Mirtazapine (Remeron); Mogadone (Nitrazepam); Molindone (Molan); Morphine; Mysoline (Primidone) & Phenobarbital; NAPA & Procainamide (Pronestyl); NAPA (N-Acetyl-Procainamide); Navane (Thiothixene); Nebcin (Tobramycin); Nefazodone (Serzone); Nembutal (Pentobarbital); Nordiazepam; Olanzapine (Zyprexa); Opiates; Orinase (Tolbutamide); Oxazepam (Serax); Oxcarbazepine (Trileptal) as 10-Hydroxyoxcarbazepine; Oxycodone (Percodan); Oxymorphone (Numorphan); Pamelor (Nortriptyline); Paroxetine (Paxil); Paxil (Paroxetine); Paxipam (Halazepam); Peganone (Ethotoin); PEMA (Phenylethylmalonamide); Pentothal (Thiopental); Perphenazine (Trilafon); Phenergan (Promethazine); Phenothiazine; Phentermine; Phenylglyoxylic Acid; Procainamide (Pronestyl) & NAPA; Promazine (Sparine); Propafenone (Rythmol); Protriptyline (Vivactyl); Pseudoephedrine;

Quetiapine (Seroquel); Restoril (Temazepam); Risperdal (Risperidone) and Hydroxyrisperidone; Secobarbital (Seconal); Sertraline (Zoloft) & Desmethylsertraline; Stelazine (Trifluoperazine); Surmontil (Trimipramine); Tocainide (Tonocard); and Topamax (Topiramate).

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76. The method of claim 57 wherein said sensor is selected from the group consisting of: metal-insulator-metal ensemble (MIME) sensors, cross-reactive optical microsensor arrays, fluorescent polymer films, surface enhanced raman spectroscopy (SERS), diode lasers, selected ion flow tubes, metal oxide sensors (MOS), bulk acoustic wave (BAW) sensors, colorimetric tubes, infrared spectroscopy, gas chromatography, semiconductive gas sensor technology; mass spectrometers, gluorescent spectrophotometers, conductive polymer gas sensor technology; aptamer sensor technology; amplifying fluorescent polymer (AFP) sensor technology; or surface acoustic wave gas sensor technology.

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77. The method of claim 76 wherein the sensor technology produces a unique electronic fingerprint to characterize the detection and concentration of said at least one target marker.

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78. The method of claim 57 further comprising the step of recording data from said sensor.

79. The method of claim 57 further comprising the step of transmitting data from said sensor.

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80. The method of claim 57 further comprising comparing at least one target marker detected with a predetermined signature profile.

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81. The method of claim 57 further comprising capturing a sample of expired gases prior to exposing said sensor to expired gases.

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82. The method of claim 57 further comprising dehumidifying expired gases prior to exposing said sensor to expired gases.

83. The method of claim 57 further comprising exposing said sensor to expired gases during exhalation of the patient's breath.

5 84. The method of claim 57 further comprising assigning a numerical value to the concentration as analyzed upon reaching a level of anesthetic effect in said patient and, thereafter, assigning higher or lower values to the concentration based on its relative changes.

10 85. The method of claim 57 wherein said sensor is portable.

86. The method of claim 57 wherein at least one therapeutic drug is a psychiatric drug.

15 87. The method of claim 86 wherein at least one therapeutic drug is selected from the group consisting of antidepressants, anti-psychotics, anti-anxiety drugs, and depressants.

88. A therapeutic drug delivery and monitoring system for delivering an appropriate dosage of the therapeutic drug to a patient:

20 at least one therapeutic drug supply having a controller for controlling the amount of therapeutic drug provided by the supply to the patient;

25 an expired gas sensor for analyzing the patient's breath for the presence and concentration of at least one target marker indicative of therapeutic drug concentrations in the patient's bloodstream, and for sending a signal regarding the concentration of the therapeutic drug in the patient's bloodstream; and

a system controller connected to the therapeutic drug supply, which receives and analyzes the signal from the sensor and controls the amount of therapeutic drug administered to the patient based on the signal.

30 89. The system of claim 88 wherein the expired gas sensor comprise a sensor for analyzing the gas for concentration of at least one target marker indicative of the therapeutic drug concentration in the patient's bloodstream and a processor for

calculating the pharmacodynamic and pharmacokinetic effect of the therapeutic drug based on the concentration of the therapeutic drug.

5 90. The system of claim 89 wherein the sensor is selected from the group consisting of: metal-insulator-metal ensemble (MIME) sensors, cross-reactive optical microsensor arrays, fluorescent polymer films, surface enhanced raman spectroscopy (SERS), diode lasers, selected ion flow tubes, metal oxide sensors (MOS), bulk acoustic wave (BAW) sensors, colorimetric tubes, infrared spectroscopy, gas chromatography, semiconductive gas sensor technology; mass spectrometers, 10 fluorescent spectrophotometers, conductive polymer gas sensor technology; aptamer sensor technology; amplifying fluorescent polymer (AFP) sensor technology; or surface acoustic wave gas sensor technology.